K073064

MAR 11 2008

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GRAFTYS®BCP
Resorbable Bone Void Filler
510(k) Summary

Prepared: October 15th, 2007

1. Submitter Information

Name :	GRAFTYS
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Telephone:	+ 33 (0) 4 42 60 30 00
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Contact:	Anthony LE NAOUR - Regulatory Manager

2. Name of Device

Trade Name:	GRAFTYS®BCP
Common Name:	Resorbable calcium salt bone void filler device
Classification name:	Resorbable calcium salt bone void filler device (CFR 888.3045 ; Product Code : MQV)

3. Legally Marketed Predicate Device

Predicate	MBCP ™ - Resorbable calcium salt bone void filler device [K051774]
	VITOSS- Resorbable calcium salt bone void filler [K994337]

4. Device Description

GRAFTYS®BCP is a sterile single use bioresorbable bone void filling substitute.
GRAFTYS®BCP is a microporous and macroporous two-phase calcium phosphate ceramic made of 60% Hydroxyapatite and 40% beta-tricalcium phosphate.
Following placement in the bony voids or gap, GRAFTYS®BCP resorbs and is replaced with bone during the healing process.
GRAFTYS®BCP is available in the form of granules, sticks, cylinders and wedges.

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5. Intended Use

GRAFTYS®BCP is intended for use as a bone void filler for voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis) caused by trauma or surgery, that are not intrinsic to the stability of the bony structure.
GRAFTYS BCP has limited initial mechanical properties. Therefore rigid fixation techniques may often be recommended.
GRAFTYS®BCP can be used with autograft as a bone graft extender.
In addition when used with appropriate opening osteotomy system devices, plates and screws, GRFATYS®BCP is intended to be used as a bone void filler in femoral or tibial osteotomies

6. Technological characteristics

GRAFTYS®BCP and the predicate device MBCP have the same technological characteristics and are osteoconductive scaffold for bone ingrowth. Both are sterile single use devices made of 60% Hydroxyapatite/40% β-Tricalcium Phosphate and have a similar porous structure (total volume ratio of 70%). As the predicate VITOSS, the interconnection between the pores is ensured by mesoporosity. GRAFTYS®BCP and predicates are provided sterile for single-use.

7. Non clinical performance data

In vitro tests, performed according to the Guidance Class II Special Controls Guidance Document: Resorbable calcium salt bone void filler device; Guidance for Industry and FDA June 2, 2003, support the substantial equivalence between GRAFTYS®BCP and the predicate device.

8. Conclusion

GRAFTYS®BCP is claimed to be substantially equivalent in term of safety and effectiveness to the predicate devices as a non structural osteoconductive bone void filler for osseous defect.

GRAFTYS – SARL au capital de 1 599 995 Euros – Siret 484 024 989 00028 – APE 244D
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Graftys
% Mr. Anthony Le Naour
415 Rue Charles Nicolas Ledoux
Eiffel Park Bat D
Aix En Provence
France 13854

MAR 11 2008

Re: K073064
Trade/Device Name: GRAFTYS®BCP – Resorbable Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 28, 2008
Received: February 1, 2008

Dear Mr. Le Naour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073064

Device Name:

GRAFTYS®BCP – Resorbable Bone Void Filler

Indications For use:

GRAFTYS®BCP is intended for use as a bone void filler for voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis) caused by trauma or surgery, that are not intrinsic to the stability of the bony structure.

GRAFTYS BCP has limited initial mechanical properties. Therefore rigid fixation techniques may often be recommended.

GRAFTYS®BCP can be used with autograft as a bone graft extender.

In addition when used with appropriate opening osteotomy system devices, plates and screws, GRAFTYS®BCP is intended to be used as a bone void filler in femoral or tibial osteotomies

Prescription Use X (Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073064